

evidence on which such determination or decision was based; or

(ii) Such initial, revised, or reconsidered determination or such decision or revised decision was procured by fraud or similar fault of the beneficiary or some other person.

[45 FR 73933, Nov. 7, 1980, as amended at 61 FR 32348, June 24, 1996; 62 FR 25853, 25855, May 12, 1997]

#### **§ 405.753 Appeal of a categorization of a device.**

(a) CMS's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 is a national coverage decision under section 1862(a)(1) of the Act.

(b) CMS's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 is an aspect of an initial determination that, under section 1862 of the Act, payment may not be made.

(c) In accordance with section 1869(b)(3)(A) of the Act, CMS's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 may not be reviewed by an administrative law judge.

[60 FR 48424, Sept. 19, 1995]

### **Subpart H—Appeals Under the Medicare Part B Program**

**AUTHORITY:** Secs. 1102, 1842(b)(3)(C), 1869(b), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395u(b)(3)(C), 1395ff(b), and 1395hh).

**SOURCE:** 32 FR 18028, Dec. 16, 1967, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

#### **§ 405.801 Part B appeals—general description.**

(a) The Medicare carrier makes an initial determination when a request for payment for Part B benefits is submitted. If an individual beneficiary is dissatisfied with the initial determination, he or she may request, and the carrier will perform, a review of the claim. Following the carrier's review determination, the beneficiary may obtain a carrier hearing if the amount remaining in controversy is at least \$100.

The beneficiary is also entitled to a carrier hearing without the benefit of a review determination when the initial request for payment is not being acted upon with reasonable promptness (as defined in § 405.802). Following the carrier hearing, the beneficiary may obtain a hearing before an ALJ if the amount remaining in controversy is at least \$500. If the beneficiary is dissatisfied with the decision of the ALJ, he or she may request the Departmental Appeals Board (DAB) to review the case. Following the action of the DAB, the beneficiary may file suit in Federal district court if the amount remaining in controversy is at least \$1,000.

(b) The rights of a beneficiary under paragraph (a) of this section to appeal the carrier's initial determination are granted also to—

(1) A physician or supplier that furnishes services to a beneficiary and that accepts an assignment from the beneficiary, or

(2) A physician who meets the conditions of section 1842(l)(1)(A) of the Act pertaining to refund requirements for nonparticipating physicians who have not taken assignment on the claim(s) at issue.

(c) Procedures governing the determinations by SSA as to whether an individual has met basic Part B entitlement requirements are covered in subpart G of this part and 20 CFR part 404, subpart J. Subparts J and R of 20 CFR part 404 are also applicable to ALJ, DAB, and judicial review conducted under subpart H, except to the extent that specific provisions are contained in this subpart.

[62 FR 25853, May 12, 1997]

#### **§ 405.802 Definitions.**

As used in subpart H of this part, the term—

*After receipt of the notice* means 5 days after the date on the notice, unless it is shown that the notice was received earlier or later.

*Appellant* designates the beneficiary, assignee or other person or entity that has filed an appeal concerning a particular determination of benefits under Medicare part B. Designation as an appellant does not in itself convey standing to appeal the determination in question.